No.	Commenter	Section/ Worksheet No.	Comment
General Comments			
G1	CPG	General	Because the LPRSA is a linked system with many of the same CSM elements, it may be beneficial to utilize the EPA-approved LPRSA PFD as a basis for the NBSA PFD, with changes, as needed, where the NBSA CSM differs, in terms of sources, pathways, and/or receptors.
G2	CPG	General	Please provide a detailed roadmap to the document. It is difficult to understand the linkage between goals, risk assessment elements, and data needs. The introduction to the Problem Formulation document (PFD) states that the PFD was prepared "to establish the overall goals, breadth, and focus of the baseline ecological and human health risk assessments." However, the document is not organized in its presentation or clear in its discussion of each of these elements. Nowhere does the document convey the goals of the baseline risk assessments (RAs), and information necessary to inform the breadth and scope of the RAs is lacking. In its current state, the PFD falls short of providing a coherent strategy for the baseline RAs or a useful "roadmap" of the steps for its execution.
G3	CPG	General	The document states that background and reference data will be used as part of the Remedial Investigation (RI), however the terms are not defined and their use in the RI and in the risk assessments in particular is unclear. Please provide detail on how background and reference data will be established for NBSA and used in the risk assessments. Please also define the terms "background" and "reference area". Will a background approach Tech Memo be generated, as was done for the LPRSA?

No.	Commenter	Section/ Worksheet No.	Comment
G4	CPG	General	The value of the PFD in the planning and design of the NBSA risk assessments and the identification of associated data needs would be improved by presenting all elements of the CSM, including sources, migration pathways, as well as potential receptors and exposure pathways. The document relies heavily on simple references to the 2011 Interim CSM (which the CPG understands is currently being revised based on significant and numerous comments from EPA). However, there is no discussion of information appearing in the interim draft CSM or previous work plans/data summaries that was considered during the risk assessment problem formulation process. While simple cut/pasting or excessive redundancy should be minimized, aspects of the Interim CSM that are relevant to this risk assessment PFD should be discussed, as opposed to simply being referenced. As example, available information on the nature and distribution of contaminants and their sources is not discussed. The presence of chemical constituents in NBSA is attributed to "a variety of sources throughout the Newark Bay area." There is no reference to the primary source of 2,3,7,8 -TCDD in the system (Lister Avenue). Additionally, NBSA sediment is not identified as a source. For the LPRSA PFD, at USEPA's direction, sediment was identified as a source. The presumption that sediment serves as a source applies to NBSA.

No.	Commenter	Section/ Worksheet No.	Comment
G5	CPG	General	Please provide additional details on potential sources as part of the overall CSM for the NBSA. In general, the current CSM needs to be presented and better described in this document, establishing pathways from sources, media, to receptors. Some of the information needed is provided in the 2011 interim NBSA CSM (Tierra 2011), however it needs to be developed further and brought into a CSM for the risk assessment purposes. In addition, the PFD does not discuss the significance and need for evaluating ongoing sources and how this ties into the CSM and use in the risk assessments.
G6	CPG	General	The document identifies and proposes to include a number of non-traditional ("emerging") chemical compounds (e.g., PCNs, PDBEs) into both future sampling and risk characterization. These compounds are not on the CERCLA Hazardous Substance List, many do not have established toxicity factors or analytical methods, and there is no precedent for their inclusion (they are not target parameters for other NY-NJ Harbor sediment site baseline HHRAs, including Gowanus Canal and LPRSA). While these chemicals may be discussed qualitatively as reflective of various compounds contributing to background, their inclusion in risk calculations introduces unnecessary uncertainty into the analysis and detracts from key site-related COPCs.
G7	CPG	General	The document lacks a discussion of modeling, including whether and how it will be incorporated into the risk assessments. Will the risk assessments rely on output of the combined LPRSA/NBSA hydrodynamic and fate and transport model? Will a bioaccumulation model be used to evaluate uptake into fish/crabs? The document should identify anticipated modeling needs, including how the models will be developed and used in the risk assessments.

No.	Commenter	Section/ Worksheet No.	Comment
G8	CPG	General	It is not clear where/when the results of the secondary data evaluation will be presented. Additional detail is needed. For consistency with the LPRSA project documents, a *Data Usability/Data Evaluation plan* that presents which data will be used in the risk assessments could be added to the list of documents to be prepared in Section 6, either as a stand-alone document or as part of the *Newark Bay RARC Work Plan*. Alternatively, this document could provide the details on the evaluation of secondary data for determining which data will be used in the risk assessment and to inform data collection needs.
G9	CPG	General	There is no discussion of how the ongoing secondary data evaluation will be documented and used in RI and risk assessment planning. The process and criteria by which existing data are being evaluated and "deemed reliable for semi-quantitative and quantitative use" in the risk assessments is a critical step in determining future data needs and objectives. The outcome of this evaluation and how it factors into data use objectives for the risk assessment and identifying future data needs should be discussed in both Section 3 (Data Summary) and Section 6 (Next Steps).
G10	CPG	General	Provide additional detail regarding the general schedule for work plans, sampling events, and production of a *Newark Bay RARC Work Plan.* Details on specific anticipated data needs are also needed.

No.	Commenter	Section/ Worksheet No.	Comment
G11	CPG	General	Focused list of chemicals for risk evaluation. It is unclear how the SLERA will be updated for a more realistic estimate of risk drivers in the BERA. Please provide methods for COPEC determination in the BERA. As stated now, it appears that many chemicals will be identified based on conservative and uncertain screening methods. This can result in the generation of a list of COPECs that is overly broad, limiting the risk assessments' value in remedial planning and decision-making. A more definitive and focused hazard identification process for the purpose of providing support to risk managers should be laid out.
G12	CPG	General	Please provide additional detail on how exposure areas will be defined and treated in the risk assessments. More specificity is needed regarding the spatial scale of assessment for human and ecological receptors.
G13	CPG	General	Specific language changes are needed to be consistent with the approach and language used in planning documents prepared with CPG and USEPA/PA.
G14	CPG	General	Please provide detail on how the Passaic River/Newark Bay hydrodynamic model, sediment transport and chemical fate and transport model will be used to support the RI. It appears the dietary model referenced in the report only is referring to a dietary dose uptake model for estimating dietary dose in wildlife based on body weight and ingestion rate and available prey tissue collected from the site. Please clarify. Please note the CPG will be completing a bioaccumulation model for the LPRSA and the NBSA as part of the LPRSA RI/FS as required by paragraph 37c of the May 2007 AOC and paragraph B.6 of the attached SOW.

No.	Commenter	Section/ Worksheet No.	Comment
Specific Comments			
S1	CPG	1.1.2	The RAGS guidance documents cited as references for conduct of the baseline HHRA are incomplete. For example, RAGS Parts B, C, E, and F are not included.
S2	CPG	1.1.2	The document states that, depending on the results of the deterministic RA, a probabilistic RA may be conducted, consistent with USEPA guidance. If a PRA is conducted, per USEPA guidance, distributions of toxicity factors or toxicity equivalency factors (TEFs) should not be included.
S3	CPG	1.2	The PFD states that the baseline HRRA will be conducted following "a two-tiered approach designed to support risk management decision-making by initially defining the constituents of potential concern (COPCs) for each medium, based on existing and new data collected during the RI, and using this information to prioritize areas requiring further assessment." The two-tiered approach is not discussed in any further detail in Section 5 of the document (BHHRA). A more complete description of the two-tiered approach is needed to understand its purpose and how it will be used to prioritize areas for further assessment.
S4	CPG	2.1	No mention of the Diamond Alkali site is included in the PFD. The presence of high levels of 2,3,7,8-TCDD due to historical releases from Lister Ave. has been established in previous documents, including the AOC, and needs to be discussed in the site history. Other in-system and background dioxin sources and the need to differentiate them from the Lister Ave. source should be discussed, including the importance of analysis of all dioxin and furan congeners for purposes source identification.

No.	Commenter	Section/ Worksheet No.	Comment
S5	CPG	Section 2.2	More specificity is needed as to how geomorphic areas relate to the exposure areas that will be evaluated for the risk assessments. Please describe how human and ecological exposure areas will be defined and evaluated.
S6	CPG	2.2.1	The current discussion of what areas of NBSA will be included in the risk assessments is unclear. What segments of the Hackensack and Kills will be included? The discussion of how differences between geographic areas will be addressed in the baseline HHRA needs clarification, including whether risks will be presented on an area-specific or site-wide basis. Does this relate to the two-tiered COPC screening process described in section 1.2, and if yes, how will the screening be performed?
S7	CPG	3	The document is an opportunity to identify issues that need to be addressed, including key questions and anticipated data needs. Where possible, the PFD should discuss the existing data set, and whether or not it can be relied upon to answer the questions. If data are not adequate, a brief description of why the data need to be augmented and how the necessary data will be generated should be included.
S8	CPG	3	The document does not fully identify the data sets that were reviewed, and where can they be found. The bases for including/ruling our specific data sets need to be described, including how specific guidance/requirements were applied.
S9	CPG	3.1.2.2	One of the five categories used to categorize shoreline access is Non-Industrial – With Residential Access. The definition of that category assumed "residential access defined as exposure for 350 days per year for 30 years." The findings of Tierra's shoreline access analysis found zero miles of NBSA fall into the category of Non-Industrial – With Residential Access. If a more realistic residential exposure definition had been used, would the outcome of the analysis change, including potential future land use?

No.	Commenter	Section/ Worksheet No.	Comment
S10	CPG	Section 3.2, Table 3-7	It is not clear where/when the results of a secondary data evaluation will be presented. Please provide details on how the determination of whether to use specific secondary data in the risk assessments will be conducted and where it will be documented.
S11	CPG	3.2.2.3	The discussion of available tissue ingestion data, which relates to human behavior and exposure, is in the section entitled Tissue Data (3.2.3), which addresses tissue chemistry and bioaccumulation data. Given the importance of the fish ingestion pathway in the baseline HHRA the available angler survey data should be discussed in a separate section focused on tissue ingestion. How will the relevance of these data in developing exposure factors for the fish/crab consumption exposure pathways be determined?
S12	CPG	3.2.2.3	Under the heading Creel/Angler Surveys, the document states there have been four major creel/angler surveys for the area in and around the NBSA, and cites May and Burger (1996), Pflugh et al. (1999), Burger et al. (1999), and Burger (2002). This should be clarified as Pflugh et al. (1999) and Burger et al. (1999) are evaluations of the same 1995 survey of the Newark Bay complex. In addition, under the discussion of Burger (2002), the document states that one of the survey locations was in the Passaic River. According to Dr. Burger's communications with the CPG, this statement is not correct. Her survey did not include the Passaic River.
S13	CPG	Section 3.2.3.1, Exhibit 3-4	Please verify that the reported average lipid for American eel from the CARP dataset is 17%. This value appears to be high.
S14	CPG	3.2.4 5.6.2.3	Surface Water Outfalls. CSO/SSO. How will CSO/SSO inputs be addressed in the baseline HHRA? Discuss why it is important that they be characterized? What data will be used? Do additional data need to be collected? Will a program for sampling CSO/SSO inputs similar to the Phase 2 sampling for the LPRSA be performed, or will these evaluations be performed based on existing data, such as sediment data within the vicinity of the outfalls? If so, which existing data sets will be considered?

No.	Commenter	Section/ Worksheet No.	Comment
S15	CPG	Section 4.1.1, page 4-1	Please describe how COPECs based on bird and mammal diet will be identified.
S16	CPG	Section 4.1.2, page 4-3	Please clarify if all 89 COPECs identified in Table 4-2 will be evaluated for each receptor group.
S17	CPG	Section 4.2, page 4-16 and 4-17	The bulleted list of representative receptors presented in the text to not match up with the receptor list presented in the CSM (Figure 4-2) (e.g., benthic infauna vs. benthic invertebrate community, pelagic invertebrates vs. plankton, pelagic fish vs. pelagic predatory fish, carnivorous birds vs. piscivorous birds). Please reconcile the terminology. Also, omnivorous mammals are included in the list of bullets on page 4-17, but not in Figure 4-2.
S18	CPG	Section 4.2, page 4-16 and 4-17, Figure 4-2	Why are insectivorous birds and mammals being evaluated as aquatic or semi-aquatic receptors? How will exposure to dietary COPECs be evaluated for these receptors (using what tissue data)?
S19	CPG	Section 4.3, page 4-16 and 4-17	The LPRSA planning documents provide receptor species/types. Please add to the document the selected receptor species that are proposed.
S20	CPG	Section 4-4, page 4-17 through 4-23	Assessment endpoints listed in the text and in Table 4-3 should be based on population/community-levels, consistent with the LPRSA planning documents: - Survival and growth of aquatic plants as a food resource of fish and wildlife populations - Survival, growth, and reproduction of invertebrate populations and community - Survival, growth, and reproduction of fish populations - Survival, growth, and reproduction of bird populations - Survival, growth, and reproduction of mammal populations
S21	CPG	Section 4.4.2, page 4-20, 2nd paragraph, Table 4-3	The inclusion of how caged in-situ eastern oyster reproductive studies relate to COPEC concentrations in sediment is unclear, as these organisms are primarily exposed to contaminants from the water column.

No.	Commenter	Section/ Worksheet No.	Comment
S22	CPG	Section 4.4.3, page 4-22, 1st paragraph, Table 4-3	Given the limited data on sediment thresholds for fish, what sediment thresholds will be used to evaluate exposure of fish to sediment?
S23	CPG	Section 4.4.3, page 4-22, 2nd paragraph	In a fish reproductive health study, the text states fish from a "reference" area would also be collected for comparison. Why is this study being conducted? This is inconsistent with the LPRSA BERA based on agreements with USEPA regarding the technical uncertainty with this test.
S24	CPG	Section 4.4.4, page 4-23	The discussion of bird egg tissues is included here and not in Table 4-3. Is the collection and evaluation of bird egg tissues included or not as a line of evidence for evaluating potential risks to birds?
S25	CPG	Section 4.4.4 and Section 4.4.5, page 4-23	Why are insectivorous birds and mammals being evaluated as aquatic or semi-aquatic receptors? How will exposure to dietary COPECs be evaluated for these receptors (using what tissue data)?
S26	CPG	Section 4.5, page 4-24, first bullet	Will all proposed surface sediments include co-located pore water data or only a subset of sediments?
S27	CPG	Section 4.5, page 4-24, third bullet	Please list specific data needs for fish: - Fish tissue (e.g., whole body, liver tissue [note this is inconsistent with the LPRSA BERA]) chemistry from the field - Fish gross internal/external health observations - Fish reproductive health data (e.g., morphology, biomarkers) and/or laboratory reproductive bioassays (note this is inconsistent with the LPRSA BERA. EPA/CPG determined the laboratory bioassays were not appropriate.

No.	Commenter	Section/ Worksheet No.	Comment
S28	CPG	Section 4.5, page 4-24, fourth and fifth bullet	Please list specific data needs for invertebrates: - Whole body invertebrate tissue chemistry from the field (e.g., blue crab, soft-shelled clam) - Laboratory and/or field invertebrate bioaccumulation tissue chemistry (e.g., *Nereis virens*, eastern oyster [*Crassotrea virginica*]) using Newark Bay surface sediment - Laboratory and/or field toxicity test on invertebrates (e.g., 10-day *Ampelisca abdita* growth, 28-day *Leptocheirus plumulosus* growth, survival, reproduction; eastern oyster reproduction) using Newark Bay surface sediment - Benthic invertebrate taxonomic data
S29	CPG	Section 4.5, page 4-24, sixth bullet	Please provide rationale and data use objectives for the collection of bird egg, feather, and/or blood tissue data. The use of these data is not included in Section 4.4.4 or Table 4-3. This is inconsistent with the LPRSA BERA.
S30	CPG	Section 4.5, page 4-24, seventh bullet	Please provide rationale and data use objective for a mammal population survey. The use of these data is not included in Section 4.4.5 or Table 4-3.
S31	CPG	4-3	Prior documents indicated that risk to reptiles will be evaluated qualitatively. Therefore, a discussion regarding the evaluation of reptiles should be added to the document.
S32	CPG	5.1	The text describing the human health CSM refers the reader to a Tierra 2011 document, and does not provide any discussion of the updated CSM. Given the importance of the CSM for guiding the BHHRA, the PFD should include a thorough summary of the human health CSM and its linkages to sources and migration pathways.
S33	CPG	5.1	The document cites an internal Tierra memorandum as one of the sources of additional information used to update the human health CSM. Has that document been approved by USEPA?
S34	CPG	Figure 5-1	Subtidal sediment is identified as a secondary source with linkage to fish and shellfish only. Direct contact with subtidal sediment is not included as a potential exposure route in the human health CSM. How is subtidal sediment defined and distinguished from intertidal sediment?

No.	Commenter	Section/ Worksheet No.	Comment
S35	CPG	5.1	The process by which it will be determined if it is necessary to include floodplain soil as a secondary source should be described.
S36	CPG	5.2	How will decreases in chemical concentrations over time be accounted for in the Feasibility Study?
S37	CPG	5.3	The document states that "where appropriate, exposure factors used for the LPRRP HHRA will be used," but no discussion is provided on how determination of "appropriateness" will be made.
S38	CPG	5.4	As discussed in Section 6, further survey work is proposed for determining shoreline access throughout the NBSA. Current and future land use scenarios for consideration in the baseline HHRA should be revisited pending the outcome of that evaluation.
S39	CPG	5.4	The document should include a table summarizing the specific receptors, relevant age groups, and exposure pathways to be evaluated for each (such as Table 4-1 of the LPRSA PFD). Scenarios that are proposed for qualitative evaluation should be identified and justified.
S40	CPG	5.4.1	Surveys and desktop evaluations performed to date have been subjective and are noted as preliminary. What additional surveys are planned? The discussion of the desktop evaluation of recreational uses of the NBSA references Appendix C as providing the list of entities contacted. This should be corrected to Appendix D.
S41	CPG	5.4.1	As described in Appendix D, the presence of marinas and kayak/canoe rental outfits in the Bay and Hackensack River should be noted. A map indicating the location of boat ramps, marinas, boat rental outfits would be helpful for identifying potential recreational points of exposure.
S42	CPG	5.5	The difference between intertidal and subtidal sediments, as it relates to human exposure, needs to be defined. Both are listed as media of interest for the baseline HRRA, "to be assessed separately." See comment #20 regarding Figure 5-1.

No.	Commenter	Section/ Worksheet No.	Comment
S43	CPG	5.5	The document states that exposure points were identified for each exposure pathway however no discussion of exposure points is included in the description of receptor scenarios. Given the scale of the NBSA, a preliminary discussion of exposure points/exposure areas for the baseline HHRA would be appropriate to include in the PFD. Is it anticipated that the HHRA will develop separate risk estimates for the various exposure points/areas based on area-specific COPCs?
S44	CPG	5.5	The second bullet at the top of page 5-8 (exposures to a transient population) is not an exposure pathway, but rather a receptor scenario.
S45	CPG	5.6.2.1	The data needs for fish/crab tissue should be specific as to tissue types (e.g., fillet for fish, and muscle/ hepatopancreas for crab etc.). In addition, a preliminary list of target species should be included. This information was included in the LPRSA PFD.
S46	CPG	5.6.2.2 and 5.6.2.3	The data needs for intertidal sediment and surface water indicate that data is needed from accessible areas. How will the determination of accessible intertidal sediments and surface water be made?
S47	CPG	5.6.2.2	Subtidal sediment is not identified as a data need, yet it is one of the exposure media of interest identified in Section 5.5. Are available subtidal sediment data sufficient for the baseline HHRA?
S48	CPG	5.6.2.3	The statement regarding the need to evaluate COPC concentrations in surface water, sediment, and tissue from regional background locations should not be limited to the surface water data needs section. As previously noted, the discussion of background should be described in the PFD.
S49	CPG	5.6.3	How will the additional data needed to estimate site-specific exposure factors be determined?
S50	CPG	5.6.3	No mention of cooking loss is included. Will cooking loss be included in the assessment of exposure from consumption of fish/crab? How will this physical process be addressed?

No.	Commenter	Section/ Worksheet No.	Comment
S51	CPG	6	Without knowing the outcome of the ongoing secondary data evaluations noted in Section 3, the data needs identified in Section 6 should be described as preliminary and subject to revision pending the outcome of these evaluations.
S52	CPG	6	Too much detail is deferred to the SAPs/QAPPs. The PFD should identify the data questions and data needs, while the SAP/QAPP should provide details on locations and numbers.
S53	CPG	Appendix B	The process of determining shoreline access relied on Google Earth imagery, ground-truthed by on-site reconnaissance when access was not clear from the imagery. Appendix B states that, "Most residentially zoned properties had fences, obstructions, or significant land elevation differences inhibiting direct contact with NBSA surface water and sediment." Were these "obstructions" visible simply relying on Google Earth imagery, or were they all ground-truthed? The shoreline type (i.e., rip rap, bulkhead, vegetated) should be included on a figure to further validate determinations regarding access to the shoreline. Will the proposed field survey/reconnaissance identified in Section 6 provide this information?